MAR 11 2003

K023121
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**510(k) Summary**

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| 1. | **Submitter:** | Orbus Medical Technologies, Inc<br>5363 NW 35th Ave<br>Fort Lauderdale, Florida 33309<br>Phone: (954) 730-0711<br>Fax: (954) 730-7601 |
| 2. | **Contact:** | Jim Clossick<br>Director of Quality Assurance and Regulatory Affairs |
| 3. | **Date Prepared:** | September 18, 2002 |
| 4. | **Device Trade Name:** | LifeStent Biliary Endoprosthesis |
| 5. | **Device Common Name:** | Biliary stent |
| 6. | **Device Classification:** | Biliary Catheter (78 FGE) |
| 7. | **Predicate Devices:** | Orbus R Stent (LifeStent) Biliary Endoprosthesis<br>IntraTherapeutics Intrastent Biliary Endoprosthesis<br>IntraTherapeutics Intrastent DoubleStrut Biliary Endoprosthesis<br>IntraTherapeutics Intrastent DoubleStrut XS Biliary Endoprosthesis<br>Cordis Palmaz Balloon Expandable Stent |

**8. Description:**

The LifeStent Biliary Endoprosthesis is a permanently implanted device used to maintain patency of a major bile duct obstructed by tissue of an impinging tumor. The device is a balloon expandable stent made by laser cutting an open lattice design into a 316L stainless steel tube. The stent is designed to be manually crimped onto a PTA balloon catheter, inserted percutaneously to the diseased site, and deployed by balloon inflation. The stents are available with an expansion range of 4.0-7.0 mm at lengths of 13, 18, 26, 36, and 56 mm.

**9. Intended Use:**

The LifeStent Biliary Endoprosthesis is intended for the palliation of malignant neoplasms in the biliary tree.

**10. Technological Characteristics:**

Comparisons of the new and predicate devices were designed to show that the technical characteristics such as materials, performance properties, biocompatibility, method of sterilization, and packaging are identical or substantially equivalent.

**11. Performance Data:**

Orbus protocols ensure that the LifeStent Biliary Endoprosthesis performs in a manner substantially equivalent to the predicate devices during *in vitro* tests such as deployment, expansion force testing, compression force testing, dimensions, expansion damage, and corrosion testing.

## 12. Conclusion

Since the LifeStent Biliary Endoprosthesis has the same intended use, identical material properties, similar performance properties, packaging, and sterilization methods, it may be considered substantially equivalent to the predicate devices cited in (7).

510(k) Number (if known): K023121

Device Name: Orbus LifeStent Biliary Endoprosthesis

FDA's Statement of the Indications For Use for device:

The Orbus LifeStent Biliary Endoprosthesis is indicated for use for the palliation of malignant neoplasms in the biliary tree.

Perscription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2003

Mr. Jim Clossick
Director of Quality Assurance
and Regulatory Affairs
Orbus Medical Technologies
5363 NW 35th Avenue
FT LAUDERDALE FL 33309

Re: K023121
Trade/Device Name: LifeStent™ Biliary Endoprosthesis
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: February 12, 2003
Received: February 14, 2003

Dear Mr. Clossick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

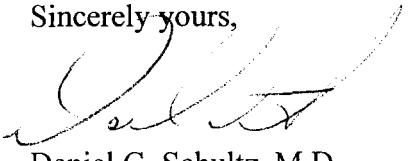
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023121

Device Name: Orbus LifeStent Biliary Endoprosthesis

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Perscription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023121